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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/303,216 04/30/99 KIM VPI97-101-CI **EXAMINER** HM12/0605 JAMES F HALEY JR ESQ ALLEN, M ART UNIT PAPER NUMBER FISH & NEAVE 1251 AVENUE OF THE AMERICAS 1631

NEW YORK NY 10020-1104

06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

		Application No.	Applicant(s)
Office Action Summary		Application No.	Applicant(s)
		09/303,216	KIM ET AL.
		Examiner	Art Unit
		Marianne Allen	1631
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status			
1)[	Responsive to communication(s) filed on 19 /	<u>March 2001</u> .	
2a)⊠	This action is <b>FINAL</b> . 2b) ☐ Th	is action is non-final.	
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims			
4)⊠	Claim(s) 1-4 and 7-24 is/are pending in the ap	pplication.	
4a) Of the above claim(s) 7-24 is/are withdrawn from consideration.			
5)	Claim(s) is/are allowed.		
6)⊠	Claim(s) <u>1-4</u> is/are rejected.		
7)	Claim(s) is/are objected to.		
8) Claims are subject to restriction and/or election requirement.			
Application Papers			
9) The specification is objected to by the Examiner.			
10) The drawing(s) filed on is/are objected to by the Examiner.			
11) The proposed drawing correction filed on is: a) □ approved b) □ disapproved.			
12)	2) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. § 119			
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) ☐ All b) ☐ Some * c) ☐ None of:			
	1. Certified copies of the priority document	s have been received.	
2. Certified copies of the priority documents have been received in Application No			
3. Copies of the certified copies of the priority documents have been received in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.			
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).			
Attachment(s)			
15) Notice of References Cited (PTO-892)  18) Interview Summary (PTO-413) Paper No(s)  16) Notice of Draftsperson's Patent Drawing Review (PTO-948)  17) Information Disclosure Statement(s) (PTO-1449) Paper No(s)  20) Other:			

U.S. Patent and Trademark Office PTO-326 (Rev. 01-01) Application/Control Number: 09/303,216

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### **DETAILED ACTION**

Claims 5-6 have been cancelled.

Claims 7-24 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made without traverse in Paper No. 8.

## Response to Arguments

Applicant's arguments filed 3/19/01 have been fully considered but they are not fully persuasive.

# Claim Rejections - 35 USC § 112

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the particular HCV NS3 helicase proteins now encompassed by the claims with a dU<sub>8</sub> oligonucleotide, does not reasonably provide enablement for all crystallizable and crystallized complexes encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to compositions capable of producing crystals for use in X-ray crystallography and crystallized complexes for use in X-ray crystallography. As set forth in the prior Office action, Brown et al. (Methods in Molecular Biology, 1996) makes clear that crystallization of protein-DNA complexes is not predictable and requires guidance and extensive experimentation that would not be considered routine to develop crystals suitable for X-ray crystallography. The reference discusses the criticality of choice of synthetic oligonucleotide used in such complexes for crystallization. (See page 300.) Applicant's amendments to the

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claims with respect to the metes and bounds of the HCV NS3 helicase protein intended and arguments regarding crystallization of highly related complexes are noted. However, it appears that the oligonucleotide portion included in or encompassed by the crystallizable composition and crystallized complex is not highly related to the dU<sub>8</sub> oligonucleotide exemplified.

Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "or nucleotide pairs." This is inconsistent with the preamble that the claimed composition itself is capable of crystallization. That is, the specification makes clear that only single-stranded oligonucleotides are crystallized not double-stranded oligonucleotides.

Claim 3 recites "single-stranded oligonucleotide ... or nucleotide pairs." The recitation of single-stranded oligonucleotides and nucleotide pairs is inconsistent and again, the specification makes clear that only single-stranded oligonucleotides are crystallized not doublestranded oligonucleotides. Note that if the nucleotide pair limitation is removed from claim 3, then claim 4 would be duplicative of this claim.

### Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO Application/Control Number: 09/303,216

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning the formalities of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 308-0009.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Aller MARIANNE P. ALLEN PRIMARY EXAMINER GROUP 1800

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